STATE OF ILLINOIS
HEALTH FACILITIES AND SERVICES REVIEW BOARD

525 WEST JEFFERSON ST. • SPRINGFIELD, ILLINOIS 62761 • (217) 782-3516 • FAX: 217) 785-4111

DOCKET NO: I-02	BOARD MEETING: December 14, 2021	PROJECT NO: 21-011	PROJECT COST:
FACILITY NAME: Physicians Surgical Centre		CITY: O'Fallon	Original: $180,000
TYPE OF PROJECT: Non-substantive			HSA: XI

PROJECT DESCRIPTION: The Applicants (Haris Assets, LLC, and O'Fallon Surgical Center LLC d/b/a Physician's Surgical Centre) proposes to add orthopedic surgical services to its current limited-specialty ambulatory surgical treatment center (ASTC) located at 741 Insight Avenue, O'Fallon, Illinois. The expected completion date is July 1, 2022, and the estimated project cost is $180,000.

The **purpose** of the Illinois Health Facilities Planning Act is to establish a procedure (1) which requires a person establishing, constructing or modifying a health care facility, as herein defined, to have the qualifications, background, character and financial resources to adequately provide a proper service for the community; (2) that promotes the orderly and economic development of health care facilities in the State of Illinois that avoids unnecessary duplication of such facilities; and (3) that promotes planning for and development of health care facilities needed for comprehensive health care especially in areas where the health planning process has identified unmet needs. Cost containment and support for safety net services must continue to be central tenets of the Certificate of Need process. (20 ILCS 3960/2)

The Certificate of Need process **required under this Act is designed to restrain rising health care costs by preventing unnecessary construction or modification of health care facilities**. The Board must assure that the establishment, construction, or modification of a health care facility or the acquisition of major medical equipment is consistent with the public interest and that the proposed project is consistent with the orderly and economic development or acquisition of those facilities and equipment and is in accord with the standards, criteria, or plans of need adopted and approved by the Board. Board decisions regarding the construction of health care facilities must consider capacity, quality, value, and equity

Information regarding this project can be found at:
https://www2.illinois.gov/sites/hfsrb/Projects/Pages/Physicians-Surgical-Center,-OFallon--21-011.aspx

EXECUTIVE SUMMARY

PROJECT DESCRIPTION:

- The Applicants (Haris Assets, LLC, and O'Fallon Surgical Center LLC d/b/a Physician's Surgical Centre) propose to add orthopedic surgical services to its existing ambulatory surgical treatment center located at 741 Insight Avenue, O'Fallon. The project costs are $180,000, and the expected completion date is July 1, 2022.
- In March of 2019 Ahmed 15, LLC, Belleville Surgical Center, Ltd d/b/a Physicians' Surgical Center purchased an ASTC located at 311 West Lincoln, Suite 300, Belleville, Illinois approved to provide Gastro procedures[#E-002-19]. In September of 2019 the Applicants were approved to relocate the ASTC to O'Fallon, Illinois [Permit #19-025] at a cost of approximately $1.3 million. The ASTC was licensed April 8, 2021. In January of 2021 the Applicants were approved to add pain management and ophthalmology services [Permit #20-041].
- The surgery center is under the ownership of Dr. Shakeel Ahmed, M.D. Dr Ahmed also owns and operates MetroEast Endoscopic Surgery Center, Fairview Heights, a multi-specialty ASTC.
- Physicians Surgical Centre currently provides the following surgical services: Gastro-Intestinal, Pain Management and Ophthalmology.
- The Applicants received an Intent to Deny at the September 14, 2021 State Board Meeting. No additional information addressing the Original State Board Staff Report findings was provided. The Applicants submittal is at the end of this report.
- The State Board Report remains unchanged from the Original State Board Report.

WHY THE PROJECT IS BEFORE THE STATE BOARD:

- The project is before the State Board because the project proposes a substantial change in scope as defined at 20 ILCS 3960/5.

PURPOSE OF THE PROJECT:

- The Applicants state: *"The primary purpose of this project is to improve access to this service for residents within the Applicants geographic service area and to increase utilization at PSC, which currently has capacity. Due to the ongoing COVID-19 Pandemic, the Ambulatory Surgery Center Association has urged the ASTCs to coordinate with local hospitals and health systems to perform elective procedures. As hospitals struggle to ensure sufficient capacity, ASTCs can serve as an alternative setting to provide care for patients who would suffer from a delay. Going forward, with the uncertainty of the lasting effects of the COVID-19 pandemic, it will be particularly important to have a non-hospital option for patients who are at high risk for severe COVID-19 illness, such as older adults or those with co-morbidities. Fortunately, orthopedic surgery cases can be safely and efficiently performed in an ASTC freestanding setting. By providing a non-hospital option for these surgical cases, the Applicant will improve patient safety".*

PUBLIC HEARING/COMMENT:

- A public hearing was offered but was not requested. Letters of support and opposition were received by the State Board.

SUMMARY:

- To add a surgical specialty to an existing ASTC an applicant must demonstrate that the proposed surgical service to be added will serve the residents of the geographical service

area; there is demand for the surgical service, the addition of the surgical service will improve service access; will not result in an unnecessary duplication of service and will meet an unmet need in the geographical service area. Under current State Board rule an existing licensed ASTC cannot add a surgical specialty unless that specialty is approved by the State Board.

- The Applicants stated the reason for the proposed project was based on increased efficiencies/access, patient convenience, and lower overall patient costs at an ASTC. In addition to the economic advantages, the Applicants also note the potential to alleviate surgical volume at hospitals located in the service area.
- Of the 45 historical referrals submitted by the Applicants 13 of the referring physician's historical patient referrals or 29% reside within the 17-mile GSA. The Applicants have not demonstrated that 50% of the orthopedic referrals to the ASTC will be serving the patients of the 17-mile GSA.
- By rule the State Board can only accept referrals from IDPH licensed ASTC or Hospitals. The State Board can only accept 2 of the 45 historical referrals: 2 referrals from Anderson Hospital because that Hospital is licensed by IDPH and is within the 17-mile GSA. The remaining 43 orthopedic procedures were performed in Missouri or at St. Joseph's Hospital in Highland which are outside the 17-mile GSA. The Missouri facilities are not licensed by IDPH. The identified demand can be accommodated with the existing capacity within the 17-mile GSA. An unnecessary duplication of service will result with the movement of these procedures from existing underutilized facilities.

Executive Summary
TABLE ONE
Referring Physician location of Orthopedic Surgery past 12-months

Facility	City	Miles	Total Cases	Proposed Referrals
Advanced Surgical Center of Sunset Hills	Sunset Hills, Missouri	33.9	7	3
Anderson Hospital	Maryville, Illinois	12.6	2	2
Apollo Surgery Center	St. Louis, Missouri	28.9	3	2
Elite Ambulatory Surgery Center	St. Louis, Missouri	28.9	3	2
St. Joseph's Hospital	Highland, Illinois	22.7	25	7
St. Louis Spine & Orthopedic Surgery Center	St. Louis, Missouri	35.4	5	0
Total			45	16

- The Applicants addressed a total of 22 criteria and have not met the following:

State Board Standards Not Met	
Criteria	**Reasons for Non-Compliance**
77 ILAC 1110.235 (c) (2) (B) – Service to Residents in the GSA	Of the 45 historical referrals 13 (29%) reside within the 17-mile GSA. The Applicants have not demonstrated that 50% of the orthopedic referrals to the ASTC will be serving the patients of the 17-mile GSA. [See pages 10-11 of this report]
77 ILAC 1110.235 (c) (3) -Service Demand	The referring physician performed 45 surgeries over the past 12-months. The Applicants are proposing to shift

State Board Standards Not Met	
Criteria	**Reasons for Non-Compliance**
	16 of these 45 referrals to the Surgery Center in O'Fallon. Two of the facilities are in Illinois, Anderson Hospital and St. Joseph Hospital and are licensed by IDPH. By rule the State Board can only accept 2 referrals: the 2 referrals from Anderson Hospital because that facility is licensed by IDPH and is within the 17-mile GSA. St. Joseph's Hospital in Highland is licensed by IDPH but is outside the 17-mile GSA. Given the small number of referrals it appears that identified demand can be accommodated with the existing capacity within the 17-mile GSA. [See pages 11-12 of this report]
77 ILAC 1110.235 (c) (6) – Service Accessibility	There are existing ASTCs and Hospitals in the 17-mile GSA. One of the ASTCs has been approved to provide orthopedic surgery services in the 17-mile GSA – Anderson Surgical Center. All the hospitals in the 17-mile GSA have the capacity to accommodate the demand identified by this application. {See page 12-13 of this report]
77 ILAC 1110.235 (c) (7) – Unnecessary Duplication of Service	There is existing capacity in the 17-mile GSA that can accommodate the workload identified by this Application. A duplication of service will result should this project be approved. [See page 13-14 of this report]

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STATE BOARD STAFF REPORT
Project #21-011
Physicians Surgical Centre, O'Fallon

APPLICATION/SUMMARY CHRONOLOGY	
Applicant(s)	O'Fallon Surgical Center LLC d/b/a Physician's Surgical Centre and Haris Assets, LLC
Facility Name	Physicians Surgical Centre
Location	741 Insight Avenue, O'Fallon, Illinois
Permit Holder	O'Fallon Surgical Centre, LLC
Operating Entity/Licensee	O'Fallon Surgical Centre, LLC
Owner of Site	Haris Assets, LLC
Gross Square Feet	N/A
Application Received	April 5, 2021
Application Deemed Complete	April 7, 2021
Financial Commitment Date	July 1, 2022
Anticipated Completion Date	July 1, 2022
Review Period Ends	June 6, 2021
Review Period Extended by the State Board Staff?	No
Can the Applicant request a deferral?	No
Expedited Review	No

I. Project Description

The Applicants (Haris Assets, LLC, and O'Fallon Surgical Center LLC d/b/a Physician's Surgical Centre) propose to add orthopedic surgical services to its current limited-specialty ambulatory surgical treatment center located at 741 Insight Avenue, O'Fallon, Illinois. No modernization/construction will occur, no operating rooms will be added, and the project costs are $180,000. The expected completion date is July 1, 2022.

II. Summary of Findings

A. State Board Staff finds the proposed project is **not** in conformance with all relevant provisions of Part 1110 (77 ILAC 1110).

B. State Board Staff finds the proposed project is in conformance with Part 1120 (77 ILAC 1120).

III. General Information

The Applicants propose to add orthopedic surgical services to its current limited-specialty ambulatory surgical treatment center (ASTC). The existing ASTC includes one procedure rooms, two Stage 1 recovery stations and two Stage 2 recovery stations and provides gastro-intestinal and pain management services. The proposed project will not introduce additional rooms to the facility, project costs total $180,000, and the expected completion date is July 1, 2022.

Physicians Surgical Centre is located at 741 Insight Avenue, O'Fallon. The surgery center is under the ownership of Dr. Shakeel Ahmed, M.D. Dr Ahmed also own and operates MetroEast Endoscopic Surgery Center, Fairview Heights, a multi-specialty ASTC.

The proposed project is a non-substantive project subject to a Part 1110 review. Part 1120 review is not applicable due to the absence of project costs.

IV. Project Uses and Sources of Funds

The Applicant a adding the orthopedic surgical specialty, the project will not result in any construction, alteration, or modification of the existing building. The $180,000 in identified project costs is for moveable equipment.

V. Background of the Applicant

A) Criterion 1110.110(a) – Background of the Applicant

An Applicant must demonstrate that it is fit, willing and able, and has the qualifications, background, and character to adequately provide a proper standard of health care service for the community. **To demonstrate compliance with this criterion the Applicant must provide**

- **A) A listing of all health care facilities currently owned and/or operated by the Applicant in Illinois or elsewhere, including licensing, certification, and accreditation identification numbers, as applicable.**
- **B) A listing of all health care facilities currently owned and/or operated in Illinois, by any corporate officers or directors, LLC members, partners, or owners of at least 5% of the proposed health care facility.**
- **C) Authorization permitting HFSRB and IDPH access to any documents necessary to verify the information submitted, including, but not limited to official records of IDPH or other State agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations. Failure to provide the authorization shall constitute an abandonment or withdrawal of the application without any further action by HFSRB.**
- **D) An attestation that the Applicant have had no *adverse action*[1] taken against any facility they own or operate, or a listing of adverse action taken against facilities the Applicant own.**

1. The Applicants supplied a list containing 2 facilities under the ownership of the Applicant. The Applicant provided a letter (application p. 50), serving as attestation that there has been no adverse action taken against facilities owned by Applicant during the three (3) years prior to filing the application.

2. The Applicant's letter on Page 50 also contains authorization permitting the Illinois Health Facilities and Services Review Board and the Illinois Department of Public Health to have access to any documents necessary to verify information submitted in connection to the Applicant's certificate of need to add surgical specialties. The authorization includes but is not limited to official records of IDPH or other State

[1]Adverse action is defined as a disciplinary action taken by IDPH, CMMS, or any other State or federal agency against a person or entity that owns or operates or owns and operates a licensed or Medicare or Medicaid certified healthcare facility in the State of Illinois. These actions include, but are not limited to, all Type "A" and Type "AA" violations." (77 IAC 1130.140)

agencies; the licensing or certification records of other states, when applicable; and the records of nationally recognized accreditation organizations.

3. The site is owned by Haris Assets, LLC, and evidence of this can be found at pages 32-41 of the application for permit.

4. Compliance with Executive Order #2006-05 and the Illinois State Agency Historic Resources Preservation Act/Flood Plains Act is inapplicable to the application for permit, because no new construction will occur.

5. Certificates of Good Standing from the State of Illinois has been provided at pages 29 and 30 of the Application for Permit. License and accreditation are provided at pages 51 through 53 of the Application for Permit.

VI. Purpose of Project, Safety Net Impact Statement and Alternatives

The following three (3) criteria are informational; no conclusion on the adequacy of the information submitted is being made.

A) Criterion 1110.110 (b) Purpose of the Project

To demonstrate compliance with this criterion the Applicant must document that the project will provide health services that improve the health care or well-being of the market area population to be served.

The Applicants state the purpose of the proposed project *"is to improve access to this service for residents within the Applicants geographic service area and to increase utilization at PSC, which currently has capacity. By providing a non-hospital option for these surgical cases, the Applicant will improve patient safety".*

B) Criterion 1110.110 (c) - Safety Net Impact Statement

This project is a non-substantive project, and a safety net impact statement is not required. The Applicants reported no Charity Care data for the two facilities under ownership/management of the Applicants (see Table One).

TABLE ONE
Charity Care Information
Physician's Surgical Centre

	2017	2018	2019
Net Patient Revenue	$5,664,920	$845,302	$48,802
Amount of Charity Care (Charges)	$0	$0	$0
Cost of Charity Care	$0	$0	$0

C) Criterion 1110.110 (d) - Alternatives to the Project

To demonstrate compliance with this criterion the Applicant must document all alternatives to the proposed project that were considered.

The Applicant considered three alternatives to the proposed project, to include the option chosen.

1) Maintain Status Quo/Do Nothing

This option would have the applicant continue in the provision of gastroenterology, pain management, and ophthalmology services at Physicians Surgical Center, leaving orthopedic procedures to be performed in one of the existing ASTCs operating in the 17-mile general service area, and at area hospitals. This option was rejected because it would not increase patient access to orthopedic surgical services or relieve operational capacity at hospitals in the service area. No project costs were identified with this alternative.

2) Utilize Other Health Care Facilities

The Applicants initially considered the option of utilizing other surgical facilities but realized only one other ASTC in the service area (Edwardsville Ambulatory Surgery Center), provided orthopedic surgical services, which would not alleviate the utilization capacities at area hospitals. This option was rejected, based on a need to increase access at the existing facility, and the need to relieve operational capacity at area hospitals. There were no project costs identified with this alternative.

3) Proposed Alternative

The Applicants chose the alternative to add the orthopedic surgical specialty, based on increased efficiencies/access, patient convenience, and lower overall patient costs. In addition to the economic advantages, the Applicants note the potential to alleviate surgical volume at hospitals located in the service area.

VIII. Project Scope and Size, Utilization and Assurances

A) Criterion 1110.120 (a) - Size of Project

To demonstrate compliance with this criterion the Applicant must document that the proposed size of the project is in compliance with the State Board Standard in Part 1110 Appendix B.

The Applicants propose to add orthopedic surgical specialty to an existing limited-specialty ASTC containing two Procedure Rooms, and six recovery stations. No new construction will occur, no space will be modernized, and the entirety of the project cost ($180,000), will be used for the purchase/installation of moveable equipment. It appears this criterion is inapplicable to the proposed project.

B) Criterion 1110.120(b) – Projected Utilization

To demonstrate compliance with this criterion the Applicant must document that the facility will be at target occupancy as specified in Part 1100.

The proposed project seeks to alleviate potential overutilization of hospital-based surgical services by adding an orthopedic surgical specialty to an existing limited-specialty ASTC. The Physicians Surgical Centre performed 104 total procedures (22 hours) (2020 IDPH hospital survey), and projects there to be 16 additional referrals (24.2 hours), due to the addition of orthopedics. It appears that the Applicants have successfully addressed this criterion.

C) Criterion 1110.120(e) – Assurances

To demonstrate compliance with this criterion the Applicant must document that the proposed project will be that by the end of the second year of operation after project completion, the Applicant will meet or exceed the utilization standards specified in Appendix B.

As documented above the State Board does not have utilization standards for the addition of surgical specialties to an existing ASTC. The Applicant attests the proposed project does not involve additional surgical suites or shell space. The Applicant has successfully addressed this criterion.

VIII. Non-Hospital Based Ambulatory Surgical Treatment Center Services

A) Criterion 1110.235(a) - 77 Ill. Adm. Code 1100 (Formula Calculation)

As stated in 77 Ill. Adm. Code 1100, no formula need determination for the number of ASTCs and the number of surgical/treatment rooms in a geographic service area has been established. Need shall be established pursuant to the applicable review criteria of this Part.

B) Criterion 1110.235(c) (2) (B) (i) & (ii) - Service to Geographic Service Area Residents

To demonstrate compliance with this criterion the Applicant must document that the primary purpose of the project will be to provide necessary health care to the residents of the geographic service area (GSA) in which the proposed project will be physically located.

i) The Applicant must provide a list of zip code areas (in total or in part) that comprise the GSA. The GSA is the area consisting of all zip code areas that are located within the established radii outlined in 77 Ill. Adm. Code 1100.510(d) of the project's site.

ii) The Applicant must provide patient origin information by zip code for all admissions for the last 12-month period, verifying that at least 50% of admissions were residents of the GSA. Patient origin information shall be based upon the patient's legal residence (other than a health care facility) for the last 6 months immediately prior to admission.

The Applicants identified a 17-mile geographic service area ("GSA") for its patient base, consisting of 35 zip codes, and a population of 412,277 residents. The Table below identifies the patient origin by zip code of residence for the prior 12-month period for the referring physician. Of these 45 historical referrals 13 (29%) reside within the 17-mile GSA. The Applicants have not demonstrated that 50% of the orthopedic referrals will be coming from the 17-mile GSA.

TABLE TWO			
Physician Historical Referrals by Zip of Patient Residence			
Zip Code	City	#	Miles from Facility
62269	O'Fallon	1	0
62294	Troy	2	9.8
62281	St. Jacob	2	14.6
62293	Trenton	3	14.7
62265	New Baden	4	16.3
62062	Maryville	1	16.8
62216	Aviston	2	19.2
62215	Albers	3	19.4
62040	Granite City	2	21.5
62249	Highland	4	22.7
62230	Breese	2	22.8
62025	Edwardsville	1	23.8
62218	Bartelso	1	27.5
62231	Carlyle	5	31.9
62275	Pocahontas	1	34.3
62088	Staunton	1	34.4
62803	Hoyleton	1	38.4
62246	Greenville	2	39.1
62284	Smithboro	2	47.3
62471	Hagarston	1	58.5
62865	Mulkeytown	1	82.3
62901	Carbondale	1	87.1
62822	Christopher	1	89.5
62906	Anna	1	126.7
Total		45	

C) Criterion 1110.235(c)(3)(A) & (B) - Service Demand – Establishment of an ASTC Facility or Additional ASTC Service

To demonstrate compliance with this criterion the Applicant must document that the proposed project is necessary to accommodate the service demand experienced annually by the Applicant, over the latest 2-year period, as evidenced by historical and projected referrals. The Applicant shall document the information required by subsection (c) (3) and either subsection (c) (3) (B) or (C):

A) Historical Referrals

The Applicant shall provide physician referral letters that attest to the physician's total number of treatments for each ASTC service that has been referred to existing <u>IDPH-licensed ASTCs or hospitals located in the GSA</u> during the 12-month period prior to submission of the application. The documentation of physician referrals shall include the following information:

i) patient origin by zip code of residence.

ii) name and specialty of referring physician.

iii) name and location of the recipient hospital or ASTC; and
iv) number of referrals to other facilities for each proposed ASTC service for each of the latest 2 years.

The referring physician performed 45 surgeries over the past 12-months in the facilities listed below. Two of the facilities are in Illinois, Anderson Hospital and St. Joseph Hospital and are licensed by IDPH. The Applicants are proposing to shift 16 of these referrals to the Surgery Center in O'Fallon. By rule the State Board can only accept 2 referrals: the 2 referrals from Anderson Hospital because that facility is licensed by IDPH and is within the 17-mile GSA. St. Joseph's Hospital in Highland is licensed by IDPH but is outside the 17-mile GSA. The identified demand can be accommodated with the existing capacity within the 17-mile GSA.

TABLE THREE
Referring Physician location of Orthopedic Surgery past 12-months

Facility	City	Total Cases	Proposed Referrals
Advanced Surgical Center of Sunset Hills	Sunset Hills, Missouri	7	3
Anderson Hospital	Maryville, Illinois	2	2
Apollo Surgery Center	St. Louis, Missouri	3	2
Elite Ambulatory Surgery Center	St. Louis, Missouri	3	2
St. Joseph's Hospital	Highland, Illinois	25	7
St. Louis Spine & Orthopedic Surgery Center	St. Louis, Missouri	5	0
Total		45	16

D) Criterion 1110.235(c)(5)(A) & (B) - Treatment Room Need Assessment

A) To demonstrate compliance with this criterion the Applicant must document that the proposed number of surgical/treatment rooms for each ASTC service is necessary to service the projected patient volume. The number of rooms shall be justified based upon an annual minimum utilization of 1,500 hours of use per room, as established in 77 Ill. Adm. Code 1100.
B) For each ASTC service, the Applicant must provide the number of patient treatments/sessions, the average time (including setup and cleanup time) per patient treatment/session, and the methodology used to establish the average time per patient treatment/session (e.g., experienced historical caseload data, industry norms or special studies).

The ASTC licensed on April 8, 2021 at the O'Fallon location. The surgery center reported two procedure rooms on its 2020 ASTC profile and 22 hours of surgery.

E) Criterion 1110.235(c)(6) – Service Accessibility

The proposed ASTC services being established or added are necessary to improve access for residents of the GSA. The applicant shall document that at least one of the following conditions exists in the GSA:
A) There are no other IDPH-licensed ASTCs within the identified GSA of the proposed project.
B) The other IDPH-licensed ASTC and hospital surgical/treatment rooms used for those ASTC services proposed by the project within the identified GSA are utilized at or above the utilization level specified in 77 Ill. Adm. Code 1100.
C) The ASTC services or specific types of procedures or operations that are components of an ASTC service are not currently available in the GSA or that existing underutilized services in the GSA have restrictive admission policies.
D) The proposed project is a cooperative venture sponsored by 2 or more persons, at least one of which operates an existing hospital. Documentation shall provide evidence that:

i) The existing hospital is currently providing outpatient services to the population of the subject GSA.
ii) The existing hospital has sufficient historical workload to justify the number of surgical/treatment rooms at the existing hospital and at the proposed ASTC, based upon the treatment room utilization standard specified in 77 Ill. Adm. Code 1100.
iii) The existing hospital agrees not to increase its surgical/treatment room capacity until the proposed project's

There is existing seven (7) IDPH licensed ASTCs including the Applicants within the 17-mile GSA [Table Four]. Under current State Board rule an existing ASTC must receive approval from the State Board to add a surgical specialty. One ASTC in the 17-mile GSA has been approved to provide orthopedic surgical services – Anderson Surgery Center. Anderson Surgery Center was license 7/23/2021. The remaining six ASTCs have not been approved to add this specialty. As seen in the Table Five below all the hospitals have existing capacity to accommodate the workload identified by this project. All the hospitals performed orthopedic procedures in 2020.

TABLE FOUR
ASTCs within the 17-mile GSA

			Miles	Rooms	Utilization
Physician's Surgical Center	O'Fallon	Limited	0	2	22
Skin Cancer Surgery Center [1]	O'Fallon	Limited	1.1	1	NA
MetroEast Endoscopy Surgery Center	Fairview Heights	Limited	5.8	2	866
Eye Surgery Center, LLC	Belleville	Limited	6	4	2,045
Bel-Clair Ambulatory Surgical Center	Belleville	Limited	9	2	139
Novamed Eye Surgery Center of Maryville	Maryville	Limited	13.6	1	803
Anderson Surgery Center [2]	Edwardsville	Multi	16.9	3	NA
Total Rooms				14	

1. Skin Cancer Surgery Center is to be completed December 2021 [Permit #19-017].
2. Anderson Surgery Center was recently licensed no utilization data available.
3. Utilization from 2020 ASTC Profiles.

TABLE FIVE
Hospitals within the 17-mile GSA [1]

Hospitals	City	Miles	OR	Hours	OR's Justified	Procedure Rooms	Hours	Procedure Rooms Justified
HSHS St Elizabeth's Hospital	O'Fallon	0.8	10	14,428	10	4	5,473	4.0
Memorial Hospital	Shiloh	2	4	3,651	3.0	2	48	1.0
Memorial Hospital	Belleville	7.8	18	8,924	6.0	15	2,343	2.0
Touchette Regional Hospital	Centreville	13.6	4	422	1.0	2	299	1.0
Anderson Hospital	Maryville	14.5	9	7,149	5.0	2	1,433	1.0
Total Rooms			45	34,574	25	25	9,596	9

1. Utilization data from 2020 Hospital Profiles.

F) Criterion 1110.235 (c) (7) - Unnecessary Duplication/Maldistribution

A) The applicant shall document that the project will not result in an unnecessary duplication. The applicant shall provide the following information for the proposed GSA zip code areas identified in subsection (c)(2)(B)(i):

i) the total population of the GSA (based upon the most recent population numbers available for the State of Illinois); and
ii) the names and locations of all existing or approved health care facilities located within the GSA that provide the ASTC services that are proposed by the project.
B) The applicant shall document that the project will not result in maldistribution of services. Maldistribution exists when the GSA has an excess supply of facilities and ASTC services characterized by such factors as, but not limited to:
i) a ratio of surgical/treatment rooms to population that exceeds one and one-half times the State average.
ii) historical utilization (for the latest 12-month period prior to submission of the application) for existing surgical/treatment rooms for the ASTC services proposed by the project that are below the utilization standard specified in 77 Ill. Adm. Code 1100; or
iii) insufficient population to provide the volume or caseload necessary to utilize the surgical/treatment rooms proposed by the project at or above utilization standards specified in 77 Ill. Adm. Code 1100.
C) The applicant shall document that, within 24 months after project completion, the proposed project:
i) will not lower the utilization of other area providers below the utilization standards specified in 77 Ill. Adm. Code 1100; and
ii) will not lower, to a further extent, the utilization of other GSA facilities that are currently (during the latest 12-month period) operating below the utilization standards.

There is a total of 84 operating/procedure rooms in the 17-mile GSA. The ratio of operating/procedure rooms per thousand population in the 17-mile GSA is .2035 per thousand population. The ratio of operating/procedure rooms per thousand population in the State of Illinois is .2083 per thousand population. To have a maldistribution of operating/procedure rooms the ratio would need to be 1.5 times the State of Illinois ratio. There is no maldistribution of operating/procedure rooms in this 17-mile GSA.

As mentioned above the State Board Staff accepted 2 surgical referral cases from Anderson Hospital in Maryville. Anderson Hospital is currently operating below the 1,500 hours per operating/procedure rooms in 2020 the most recent data available. The approval of the orthopedic surgery services at the ASTC will result in a lowering of the utilization of the operating rooms at the Anderson Hospital in the area [Table Six].

TABLE SIX
Hospitals in which physician will redirect orthopedic cases to Surgery Center.

Hospital	City	Miles	Operating Rooms	Hours	Operating Rooms Justified
Anderson Hospital	Maryville	14.5	9	7,149	5

G) Criterion 1110.235(c)(8)(A) & (B) - Staffing

A) Staffing Availability

To demonstrate compliance with this criterion the Applicant must document that relevant clinical and professional staffing needs for the proposed project were considered and that the staffing requirements of licensure and The Joint Commission or other nationally recognized accrediting bodies can be met. In addition, the Applicant shall document that necessary staffing is available by providing letters of interest from prospective staff members, completed applications for employment, or a narrative explanation of how the proposed staffing will be achieved.

B) Medical Director

It is recommended that the procedures to be performed for each ASTC service are under the direction of a physician who is board certified or board eligible by the appropriate professional standards organization or entity that credentials or certifies the health care worker for competency in that category of service.

Physicians Surgical Centre anticipates the satisfactory provision of services using existing staff and notes the ASTC is staffed in accordance with IDPH and Medicare staffing requirements.

H) Criterion 1110.235(c)(9)-Charge Commitment

To meet the objectives of the Act, which are *to improve the financial ability of the public to obtain necessary health services; and to establish an orderly and comprehensive health care delivery system that will guarantee the availability of quality health care to the public; and cost containment and support for safety net services must continue to be central tenets of the Certificate of Need process* [20 ILCS 3960/2], the Applicant must submit the following:

A) a statement of all charges, except for any professional fee (physician charge); and

B) a commitment that these charges will not increase, at a minimum, for the first 2 years of operation unless a permit is first obtained pursuant to 77 Ill. Adm. Code 1130.310(a).

A list of procedures by primary CPT code for the proposed new orthopedic specialty with the maximum charge has been provided as required (application page 73) and attests that the charges for these procedures will not increase in the two years following project completion. The Applicants have met the requirements of this criterion.

I) Criterion 1110.235(c)(10)(A) & (B) - Assurances

To document compliance with this criterion

A) The Applicant must attest that a peer review program exists or will be implemented that evaluates whether patient outcomes are consistent with quality standards established by professional organizations for the ASTC services, and if outcomes do not meet or exceed those standards, that a quality improvement plan will be initiated.

B) The Applicant shall document that, in the second year of operation after the project completion date, the annual utilization of the surgical/treatment rooms will meet or exceed the utilization standard specified in 77 Ill. Adm. Code 1100. Documentation shall include, but not be limited to, historical utilization trends, population growth, expansion of professional staff or programs (demonstrated by signed contracts with additional physicians) and the provision of new procedures that would increase utilization.

The Applicants attest that a peer review program exists, and the added surgical specialty will aid in the achievement and maintenance of sufficient operational capacities to satisfy the State standard by the second year after project completion.

IX. Financial Viability

A) Criterion 1120.120 – Availability of Funds
B) Criterion 1120.130 - Financial Viability

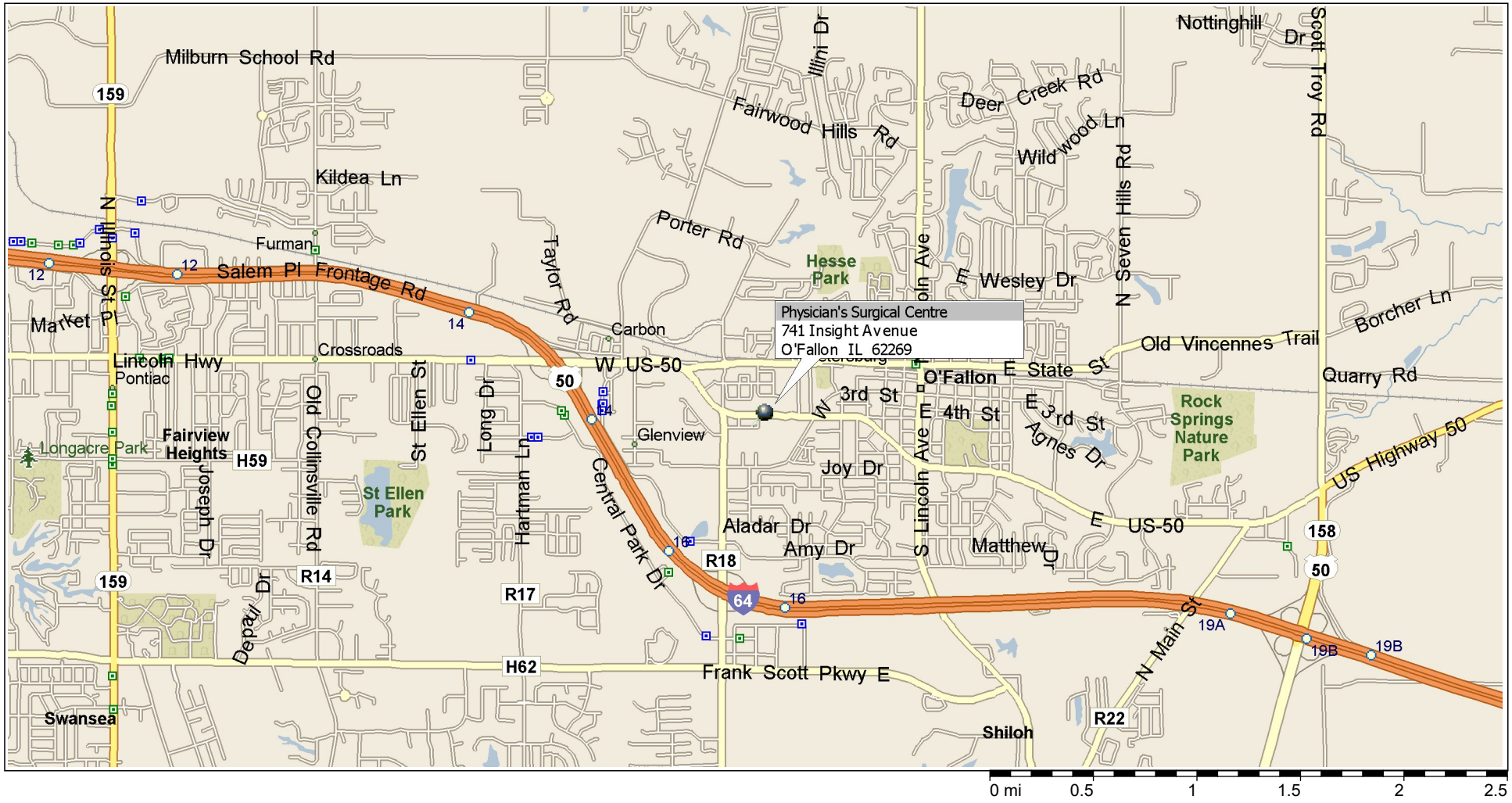
The Applicant notes the project seeks to add one surgical specialty, changing the designation from limited specialty to multi-specialty. No new construction will occur, and the entirety of the project funding will be used for the purchase of moveable equipment.

X. Economic Feasibility

A) Criterion 1120.140(a) –Reasonableness of Financing Arrangements
B) Criterion 1120.140(b) – Conditions of Debt Financing
C) Criterion 1120.140 (c) – Reasonableness of Project Costs
D) Criterion 1120.140(d) – Projected Direct Operating Costs
E) Criterion 1120.140(e) – Total Effect of the Project on Capital Costs

The Applicants are adding orthopedics surgical specialty to an existing ASTC, with no construction/modernization costs. The Applicants identified $180,000 in project costs and attribute these costs to the purchase of moveable equipment. The Applicants are funding the project in its entirety with cash and securities; therefore, these criteria are inapplicable.

#21-011 Physicians Surgical Centre - O'Fallon



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September 23, 2021

Anne M. Cooper
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Via Email

Ms. Courtney Avery
Administrator
Illinois Health Facilities and Services Review Board
525 West Jefferson Street, 2nd Floor
Springfield, Illinois 62761

Re: Physicians' Surgical Centre (Proj. No. 21-011)
Request to Reappear

Dear Ms. Avery:

This office represents Physicians' Surgical Centre (the "Applicant"). In this capacity, we are writing in response to the Illinois Health Facilities and Services Review Board's ("HFSRB") issuance of an intent to deny the Applicant's proposal to add orthopedic surgery at its existing ambulatory surgical treatment center located at 729 Insight Avenue, O'Fallon, Illinois. Pursuant to Section 1130.670 of the HFSRB's rules, the Applicant respectfully requests to reappear before at the October 26, 2021 HFSRB meeting.

The Applicant does not intend to submit additional information as the certificate of need application, comments to the State Board Report, and presentation at the September 14, 2021 HFSRB meeting support approval of the addition of orthopedics as Physicians' Surgical Centre.

In response to questions at the September 14, 2021 HFSRB meeting, the Applicant confirmed it has approximately 50,000 patients who receive care in the affiliated medical practice, about one-third of whom are Medicaid beneficiaries. As was stated in the hearing, while there is no standard of minimum number of cases to add a surgical specialty to an existing surgery center, Dr. Ahmed has a history of treating indigent patients who cannot receive care at the local hospitals and if they have orthopedic needs, he would expect to refer them to orthopedic surgeons who would be offered medical staff members at the surgery center (upon completion of the credentialing process). Such outpatient orthopedic surgeries are vital to improving a patient's quality of life but rarely require an overnight stay or other higher cost hospital-based services. Without the approval of this application, residents of O'Fallon and immediately surrounding areas

who want a lower cost option for orthopedic care must travel to St. Louis or other distant Illinois communities. These patients will continue to migrate out of their communities for care unless there is an alternative in the Metroeast region to the local hospitals.

Separately, to address Member Kaatz's concern regarding performing gastroenterology procedures and orthopedic procedures in the same operating room, the Centers for Medicare and Medicaid Services eliminated the distinction between sterile operating rooms and non-sterile procedure rooms in 2009, so the surgery center complies with the same standards as sterile operating rooms. See Attached "Guidelines for Safety in the Gastrointestinal Endoscopy Unit." Orthopedic procedures will be performed in sterile environment. As staff knows, the surgery center currently is approved to provide a variety of surgical specialties, not solely endoscopy, and these services all meet the standard of care.

Thank you for consideration of the Applicant's request to reappear at the October 26, 2021 HFSRB meeting

Sincerely,

A. M. Cooper

Anne M. Cooper

Attachment
cc: Dr. Shakeel Ahmed

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Guidelines for Safety in the Gastrointestinal Endoscopy Unit

Audrey H. Calderwood, MD, **Frank J. Chapman, MBA**, **Jonathan Cohen, MD**, **Lawrence B. Cohen, MD**, **James Collins, BS, RN, CNOR**, **Lukejohn W. Day, MD**, and **Dayna S. Early, MD**

EXECUTIVE SUMMARY

Historically, safety in the gastrointestinal (GI) endoscopy unit has focused on infection control, particularly around the reprocessing of endoscopes. Two highly publicized outbreaks where the transmission of infectious agents were related to GI endoscopy have highlighted the need to address potential gaps along the endoscopy care continuum that could impact patient safety.

In 2009, the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage eliminated the distinction between a sterile operating room and a non-sterile procedure room. Hence, GI endoscopy units are now held to the same standards as sterile operating rooms by CMS[1] without evidence demonstrating that safety or clinical outcomes in endoscopy are thereby improved. Although the ASGE has previously published guidelines on staffing, sedation, infection control, and endoscope reprocessing for endoscopic procedures (*Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011; Infection control during GI endoscopy; Minimum staffing requirements for the performance of GI endoscopy; Multisociety sedation curriculum for gastrointestinal endoscopy*)[2, 3, 4, 5] the purpose of this document is to present recommendations for endoscopy units in implementing and prioritizing safety efforts and to provide an endoscopy-specific guideline by which to evaluate endoscopy units. As a general principle, requirements for safety ought to be rooted in evidence that demonstrates a benefit in outcomes. Where data is absent, these requirements may be derived from experts with experience in the safe delivery of care in the GI endoscopy setting. Additionally, consideration should be given to the promotion of efficient care and cost containment with avoidance of requirements unsupported by evidence that then contribute to rising healthcare costs.

Over the past 2 years, surveyors have called into question accepted practices at many accredited endoscopy units seeking re-accreditation. Many of these issues relate to the Ambulatory Surgical Center (ASC) Conditions for Coverage set forth by CMS and the lack of distinction between the sterile operating room and the endoscopy setting. The following is a summary of issues that have been faced by endoscopy units throughout the country along with ASGE's position and accompanying rationale.

- **Issue:** Structural requirements for 40-inch doors and room sizes >400 square feet required of sterile operating rooms.

  Position: Standard 36-inch doors, if they accommodate patient transport mechanisms, and room sizes 180 square feet are adequate and safe for endoscopy

units because they do not use the same large equipment or number of staff as in the operating room.[6]

- **Issue:** Requirement for a written policy on traffic patterns in the endoscopy unit.

  Position: The unit should define low-risk exposure and high-risk exposure areas and activities within the endoscopy unit, and describe the attire and personal protective equipment that should be worn in each area. Endoscopy staff can move freely throughout the unit provided that there is appropriate use and changing of personal protective equipment.

- **Issue:** Requirement for endoscopy personnel to don full sterile operating room personal protective equipment including new scrubs, hair covers and booties.

  Position: It is recommended that staff directly engaged in GI endoscopy or in processes where splash or contamination could occur should wear gloves, face/eye shields, and an impervious gown. Units should develop policies that are consistent with OSHA and state-mandated recommendations for wearing face/eye shields or masks.[7] Scrubs or other attire may be worn from home because endoscopy is not a sterile procedure. Likewise, there is no need for hair covers or booties. Staff must remove and appropriately discard used PPE before leaving the procedure area.

- **Issue:** Supervision of moderate sedation.

  Position: Moderate sedation may be administered safely under the supervision of a non-anesthesia physician who is credentialed and privileged to do so.

- **Issue:** Role of capnography.

  Position: There is inadequate data to support the routine use of capnography where moderate sedation is the target.

- **Issue:** Requirement that 2 nurses (one monitoring, one circulating) are present when moderate sedation is performed.

  Position: When moderate sedation is the target, a nurse should monitor the patient and can perform interruptible tasks. If more technical assistance is required, a second assistant (nurse, licensed practical nurse, or unlicensed assistive personnel) should be available to join the care team.

- **Issues:** Staffing requirements when sedation and monitoring is provided by anesthesia personnel.

  Position: When sedation and monitoring is provided by anesthesia personnel, a single additional staff person (nurse, licensed practical nurse, or unlicensed assistive personnel) is sufficient to assist with technical aspects of the procedure.

- **Issue:** Technical capabilities of technicians.

  Position: Unlicensed technicians, who have received initial orientation and ongoing training, and are deemed competent by their unit, can assist with and participate in tissue acquisition during the endoscopic procedure, including but not limited to the opening and closing of forceps, snares, and other accessories.

BACKGROUND

The overall risk of transmission of healthcare-associated infections (HAIs) during the performance of endoscopic procedures is estimated to be very low.[8] Historically, according to the Centers for Disease Control and Prevention, most cases have occurred from a breach in proper cleaning and disinfection of endoscopic equipment. Despite the low risk of HAIs

from endoscopic procedures, recent outbreaks of certain hospital-based HAIs, such as *Clostridium difficile* (*C difficile*) and methicillin-resistant *Staphylococcus aureus* (MRSA), have brought HAIs to the attention of hospital administrators and other stakeholders and have raised the public's concern over safety in hospitals. In addition, several highly-publicized cases of Hepatitis C infection in the outpatient endoscopy setting have heightened interest in ensuring safety in ambulatory endoscopy centers and office-based endoscopy units. The outbreak of Hepatitis C among patients undergoing endoscopy at 2 facilities owned by a single physician in Nevada was attributed to improper injection techniques, whereas an infection control breach among patients who underwent colonoscopy at 2 Veteran's Administration Medical Centers in Florida and Tennessee was attributed to installation of an improper irrigation valve on the endoscope and failure to change irrigation tubing between cases.[9, 10] Although the risk of infections from endoscopic procedures, regardless of the setting, remains low, these cases highlight the need to address potential gaps along the endoscopy care continuum that may impact patient safety outcomes.[2, 3, 4, 5]

Changes to the Centers for Medicare and Medicaid Services (CMS) ASC Conditions for Coverage that went into effect in 2009 eliminated the distinction between a sterile surgical room and a non-sterile procedure room providing further impetus for this guideline. As a result of these conditions, non-sterile procedure environments, including endoscopy units, are now held to the same standards as sterile operating rooms even though requirements for facilities, infection control, staffing and sedation applicable to the sterile operating room may not be relevant or necessary for endoscopy units. To date, the Association of periOperative Registered Nurses (AORN) and other organizations have set standards for sterile operating environments.[11] This document is endorsed by organizations with specific expertise in the safe delivery of care in the non-sterile, GI endoscopy environment which recognize the important distinction between the endoscopy and sterile operating room settings. Safety in the gastrointestinal endoscopy unit begins with clear and effective leadership that fosters a culture of safety including team work, openness in communication, and efforts to minimize adverse events. Although issues of governance and culture are important, they are outside the scope of this document.

Facilities

Facilities are the foundation of a unit, the layout of which should provide a safe environment for patients and staff. Facilities should be designed to comply with local and state building codes as well as the National Fire Protection Association (NFPA) 101 Life Safety Code.[12] The specific version of the Code will depend upon currently accepted practice for CMS and state regulations.[13, 14] Recommendations for facility standards are largely based on expert opinion and put into practice by accreditation bodies; however, no association with patient outcomes has been shown.

Recommendations for Architectural Layout—Each unit should have a designated flow for the safe physical movement of dirty endoscopes that does not cross-contaminate clean endoscopes coming out of the cleaning process and their storage. Although circular flow is preferable, some units may be constrained by the existing footprint of the facility.

Recommendations for the Endoscopic Procedure Room—Endoscopic procedure rooms will vary in size, with more complex procedures, such as endoscopic retrograde cholangiopancretography (ERCP), requiring greater space for more specialized equipment and possibly additional staff. For endoscopy, procedure rooms should not be held to the same standards as sterile operating rooms, which require space for anesthesia support, a greater number of staff members and bulkier equipment, none of which are essential for the

performance of endoscopy. Standard endoscopic procedures will require less space, with requirements varying from as little as 180 square feet to 300 square feet.[6]

The following are issues within the endoscopic procedure room that are related to patient safety:

- Actual marking of the site is not required for endoscopic procedures as endoscopy does not involve lateral right/left distinction levels such as those found in spinal procedures or multiple structures such as fingers or toes. Before starting an endoscopic procedure, the patient, staff and performing physician should verify the correct patient and procedure to be performed.
- A reliable and adequate source for oxygen is required. Sources may include in-wall or free-standing oxygen. In some units, carbon dioxide may be used for insufflation of the gastrointestinal lumen, but this is not a requirement.
- A suction source for the equipment and patient must be present either in-wall or portable. For tubing and portable suction, the manufacturer's guidelines must be followed.
- An uninterruptible source of power, supplied either by a generator or battery source is required. The purpose of a secondary power source is to finish the current procedure in the event the primary power source malfunctions. Procedures should not be started when the only source of power is the secondary source.
- Units must practice fire safety in adherence with the NFPA 101 Life Safety Code.[12]
- The number and type of electrical outlets tied to the generator is dictated by the NFPA 101 Life Safety Code, which recommends that not all outlets be tied to the generator in case the generator fails to disengage once power is restored.[12] The unit's defibrillator and crash cart should be checked at the beginning of each day to ensure that all components are functional, fully stocked, and readily accessible.
- The routine monitoring of temperature and humidity within the endoscopic procedure area, although advocated by CMS to theoretically curtail growth of microorganisms and reduce fire hazard, has not been associated with safety outcomes in endoscopic units. In the absence of published guidelines on the optimal ranges for these parameters, routine monitoring of temperature and humidity is not currently warranted.[1]
- Puncture resistant containers for biohazardous materials and sharps should be located so that sharps are not passed over the patient.[15]
- if special therapeutic procedures are planned, specific room features may be required, such as leaded walls when flat table fluoroscopy is utilized.[16]

Recommendations for the Endoscopic Recovery Area

- The recovery bays should provide privacy and sufficient space for monitoring and care. The minimum space per bay has not been established. Unit facilities must be able to provide the level of recovery appropriate to the level of sedation utilized.[17]

Recommendation for Storage of Supplies

- Sterile supply items such as intravenous (IV) solutions should be protected from splash contamination during environmental cleaning (8 to 10 inches off the floor), damage from compression (stacking only ridged containers), and water damage (no storage under sinks).

- Units should have a process for periodically verifying that supplies marked with an expiration date have not expired. Compliance with this process should be documented.

Infection Control

ASGE has published several guidelines detailing ways to minimize the risk of transmission of infection within the endoscopy unit.[2, 18] In addition to meticulous endoscope reprocessing, a specific infection prevention plan must be implemented to prevent the transmission of pathogens in the unit and to provide guidance should a breach occur. Active Infection Prevention Surveillance programs and ongoing educational and competency evaluation of staff regarding activities within the pre-, intra-, and post-procedure phases are necessary to ensure overall safety of patients and healthcare workers. Infection prevention plans for a specific unit must be directed by a qualified person. Although state regulations may vary, CMS allows the unit to designate the specific training and competency of the individual.

The Infection Prevention Plan must be documented in writing and should include a set of policies and procedures appropriate for and targeted to the specific procedures performed in addition to likely sources of nosocomial infection in the unit. The plan should include a process for the ongoing assessment of compliance with the program and methods for correction.

Standard Precautions, the minimum infection prevention practices applicable to all patient care regardless of the suspected or confirmed infection status of the patient, are the foundation of a sound infection prevention strategy. These include:

- Hand hygiene
- Personal protective equipment
- Safe medication administration practices
- Safe handling of potentially contaminated equipment or surfaces in the patient environment.[19]

Recommendations for Hand Hygiene—Proper hand washing is considered to be the cornerstone of preventing the transmission of pathogens.

- Hand hygiene should be performed before patient contact (even if gloves are to be worn), after patient contact and before exiting the patient care area, after contact with blood, body fluids or contaminated surfaces (even if gloves are worn), before performing invasive procedures (i.e., placement or access of intravascular lines) and after glove removal.[20]
- The use of soap and water is required when hands are visibly soiled and after caring for patients with known or suspected infectious causes of diarrhea such as *C. difficile*. Otherwise, the use of alcohol-based hand agents is adequate.[21]

Recommendations for Personal Protective Equipment—The unit should have a written policy and procedure regarding personal protective equipment (PPE) that defines activities in which PPE should be worn and the appropriate type. [22] For sterile environments, the use of PPE is commonly dictated by the traffic pattern and location of care, defined as unrestricted, semi-restricted, and restricted areas.[23] In contrast, in the non-sterile endoscopy environment, the use of PPE is dependent on the degree to which staff has the potential to come into direct contact with patients and their bodily fluids during specific

activities, rather than the location of care. The risk of exposure can be categorized into low-risk exposure and high-risk exposure, which are defined as follows:

- Low-risk exposure: Any personnel not in direct contact with a contaminated endoscope, device or bodily fluid or with the potential for splash contamination. For example, personnel entering the procedure area for a brief period of time who are not involved in direct patient care are considered at low-risk exposure.
- High-risk exposure: Any personnel working in direct contact with a contaminated endoscope, device or bodily fluid or any personnel in direct patient care with the potential to come into contact with a contaminated endoscope, device or bodily fluid.

Low-risk exposure activities require no PPE. Personnel whose exposure status may change during an endoscopy procedure should have immediate access to PPE should the need arise.

High-risk exposure activities require the use of gloves and impervious gowns. Due to the potential for splash exposure to the face, individual units should develop policies based on OSHA and state-mandated recommendations for wearing face/eye shields or masks.[8] Hair and shoe covers and gown classifications above AAMI Level 1 are often included in PPE recommendations.[24] These items are generally mandated for the sterile operating room environment but there is no evidence to support their requirement or benefit in the non-sterile endoscopy environment.

- Staff must remove and appropriately discard used PPE before leaving the procedure room. PPE should not be reused or worn to care for more than one patient.
- Scrub attire may be worn from home, as endoscopic procedures are performed in a non-sterile environment.
- Individuals may elect to wear regular clothing covered by an impervious gown. There is no requirement to change clothing once the individual arrives at work.
- if clothing under the procedure room attire is contaminated with a significant amount of blood or body fluids, the items should be placed in a bag, identified as a potential biohazard, then sent for cleaning to a laundry facility capable of properly cleaning and disinfecting clothing used in the health care settings.

Recommendations for Safe Medication Administration Practices—Safe medication administration practices promote safety in medication administration and have become a highly-scrutinized activity within healthcare[25] in part because of evidence of pathogen transmission resulting from the improper use or reuse of syringes, multiple-dose drug vials, and IV equipment. The Centers for Disease Control and Prevention (CDC) and ASGE have issued guidelines outlining safe injection practices.[19, 26] Units should adhere to the following:

- If a unit draws up medications for multiple patients, it should be done in an area away from direct patient care or procedure rooms.
- Units should appropriately label all medications, including those used for sedation unless the medication is for immediate use (defined as drawn up and administered immediately without leaving the provider's hand).[26]
- Units should limit the use of medications marked either on the container or noted in the package insert as "single patient use" to a single patient only and discard any remaining drug.
- Units should use new fluid administration sets (e.g., IV tubing) for each patient.

- Units should prepare and administer injections using aseptic technique (i.e., cleansing the access diaphragms of medication vials with 70% alcohol before inserting a device in the vial). Single-dose vials, ampules, bags, or bottles of IV solution should only be used for a single patient.
- Use of a single-dose vial is preferred over multi-dose vials (MDV), particularly when medications will be administered to multiple patients.[3]
- If MDV will be used for more than one patient, they should remain in a centralized medication area and should not enter the patient procedure area. These should be dated when opened and discarded according to protocols in compliance with nationally accepted guidelines, such as those published by the CDC.[27]
- Units should not re-use a syringe to enter a medication vial or solution, even with a new needle.
- Units should not use the same syringe to administer medications to multiple patients regardless of whether the needle is changed or an intervening length of IV tubing is used.
- Units should dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant and leak-proof.[28]
- Units should develop a clearly-defined policy for the management of sharps and sharps-related injuries, including the reporting of blood and body fluid exposures. This should be in compliance with federal, state and local guidelines.
- Units should consistently maintain a log of sedation medications wasted between patients that can be used to reconcile used and wasted vials at the end of the day.
- If tubes of lubricant are used for more than one exam, the unit should observe appropriate infection control habits and discard any tube that has potentially been contaminated.
- Although the multisociety guideline recommends using sterile water in the irrigation bottle, it is acceptable to use tap water as this has been shown to be safeinformed co.[29] The rates of bacterial cultures are no different with the use of tap water versus sterile water and neither has been associated with clinical infections.[30, 31]
- Units should follow federal and state requirements for the protection of health care personnel from exposure to blood-borne pathogens.

Recommendations for Safe Handling of Potentially Contaminated Equipment or Surfaces—Environmental cleaning of surfaces is mandatory with an appropriate Environmental Protection Agency labeled disinfectant, emphasizing surfaces that are most likely to become contaminated with pathogens, such as those in close proximity to the patient (e.g., side rails) and other frequently-touched surfaces in the unit. Facility policies and procedures should address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious material.[20, 32] Units should:

- Maintain Material Safety Data Sheets (MSDS) for all chemicals used for cleaning and disinfection. These sheets should detail the safe and proper use and emergency protocol for a chemical. MSDS should be used for training staff on each chemical's safe use.
- Follow the manufacturer's directions for surface disinfection of patient care items.

  - Appropriate contact time of disinfectant to achieve germicidal kill should be followed.
  - Alcohol should not be used to clean environmental surfaces.
- Properly clean and disinfect surfaces that are frequently touched by personnel or dirty equipment in the endoscopic procedure area at the beginning of the day, between cases, and during terminal cleansing. Frequently touched surfaces may include endoscopy keyboards, video monitors and consoles.

Terminal Cleansing—Terminal cleansing involves the cleaning of surfaces to physically remove soil and biofilm, followed by proper disinfection. Typically, this requires use of 2 distinct agents because chemical disinfectants are not effective at cleansing and cleansing agents are not effective at disinfecting surfaces.

- The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.
- Agents for terminal cleansing should have efficacy in spore removal, which may differ from requirements for agents used in sterile operating rooms.
- Before the first case of the day, staff should verify that all procedural and recovery areas have been properly cleansed.
- A training and competency assessment program should be in place for staff that is involved in terminal cleansing to ensure proper and safe handling and use of the chemicals.

Reusable Medical Equipment—The reprocessing protocol of reusable medical equipment such as endoscopes and endoscopic accessories must be strictly followed.[3] The details of reprocessing according to their Spaulding Classification are well described.[33] These policies should be a part of the unit's policies and procedures and core competency assessment.

Single-use devices (SUD) as determined by the manufacturer label or packaging insert may not be reprocessed unless they are specifically listed in the Food and Drug Administration (FDA) 510(k) database. If so, they must be reprocessed by entities that have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs.[34]

Written policies and procedures regarding infection control for a unit should be documented.

Staffing

Staffing requirements for the performance of GI endoscopy should be based on what is required to create a safe environment for the patient and to ensure the safe performance of the endoscopic procedure. The minimum safe staffing of an endoscopy room is outlined in the ASGE's *Minimum staffing requirements for the performance of GI endoscopy.*[4] For patients undergoing routine endoscopy under moderate sedation, a single registered nurse (RN) is required. There is no evidence that staffing beyond a single RN improves the safety of the patient. There are some circumstances in which additional assistance can be helpful for the technical aspects of the procedure, such as in ERCP, yet there is no published safety or clinical outcomes data to support the routine use of a circulating nurse for endoscopic procedures. Guidelines for staffing requirements in other settings, such as the sterile operating room, do not apply to the endoscopic procedure room because of inherent differences in these settings.[35]

Both patient and procedural factors should be considered in determining staffing requirements. Patient factors that affect staffing requirements include the level of sedation that is planned (i.e., whether the patient is receiving no sedation, moderate sedation or deep sedation) and the medical condition of the patient, which is determined from the history and physical exam and is reflected in the American Society of Anesthesiology (ASA) classification of the patient. Procedural factors include the anticipated length of the procedure and whether the procedure is intended to be diagnostic or if a therapeutic intervention is planned. Complex interventional procedures, such as endoscopic ultrasound (EUS) and ERCP may require additional staff for efficiency, but there is no evidence to suggest that this improves safety or patient outcomes.

Staffing Recommendations for Pre-procedure care

- Staffing models in the pre-procedure area should support activities required to prepare patients for endoscopy.
- The ratio of RNs to patients in the pre-procedure is variable depending on the acuity of the patients.

Staffing Recommendations for Intra-procedure care based on level of sedation[4]

- No sedation—One assistant (RN, LPN, or unlicensed assistive personnel (UAP)) other than the physician performing the procedure should be present to assist with the technical aspects of the procedure.
- Moderate sedation (also known as conscious sedation)—Sedation should be directed by the physician who is credentialed and privileged to do so and can be administered by an RN. During the period in which the patient is sedated, the RN must monitor the patient for vital sign changes, hypoxemia and comfort. The RN may assist with minor, interruptible tasks. In the event that more intense technical assistance is required, a second assistant (RN, LPN, or UAP) should be available to join the care team for the technical aspects of the procedure.
- Deep sedation—Most institutions require that deep sedation be administered by an anesthesia professional such as an Anesthesiologist, Certified Registered Nurse Anesthetist (CRNA), or Anesthesiologist Assistant who are credentialed and privileged to do so. In this situation, the anesthesia provider should be responsible for administering sedation and monitoring the patient. A second staff person (RN, LPN, or UAP) is required to assist with technical aspects of the procedure.[4,17]

Staffing Recommendations for Post-procedure care

- An RN is required to monitor patients who have received sedation until the patient is stabilized and to assess for adverse events related to the endoscopic procedure.
- Once the patient is stable, post-procedure activities such as providing food or drinks and assistance in changing clothes can be performed by an RN, LPN or UAP.
- The ratio of RNs to patients in the post-procedure setting is variable depending on the acuity of the patients.

Training Recommendations

- Sedation—Sedation should be administered by an RN under the supervision of the endoscopist who is credentialed and privileged to do so, or by anesthesia personnel (physician or CRNA) who are credentialed and privileged to do so. These

individuals should be specifically trained in endoscopic sedation, including the modes of action and adverse events of the sedative agents being used. This training should be documented. The staff administering sedation must have the knowledge and skills to recognize when the sedation level becomes deeper than planned and to manage and support patients' cardiopulmonary response to sedation accordingly. Upon verification of training, the unit should document the privileging of the RN to provide moderate sedation under the direct supervision of a physician. LPNs and UAPs are not qualified to administer sedation.

- Technical assistance—Technical assistance can be provided by a variety of staff members, including UAPs, LPNs, RNs and GI technicians. Training in the use of endoscopic equipment, accessories, and ancillary equipment should be documented and include an objective assessment of initial competence and annual competency testing thereafter to ensure and document that skills are maintained.
- Basic and Advanced Cardiac Life Support - All staff with clinical responsibilities must have Basic Life Support (BLS) certification. At least one individual with Advanced Cardiac Life Support (ACLS) certification must be present in the unit when patients are present.
- A written policy on staff training along with type and frequency of core competency assessment should be documented.

Endoscopic Sedation

Sedation can improve the quality of GI endoscopy, the likelihood of a thorough and complete examination, patient satisfaction, and patient willingness to undergo (re)examination. The choice of specific sedation agents and the level of sedation targeted should be determined on a case-by-case basis by the endoscopist in consultation with the patient. Unsedated endoscopy may be appropriate in some instances. For a detailed discussion including supporting evidence, please refer to the 2008 ASGE guideline on *Sedation and Anesthesia in GI Endoscopy*.[17]

Recommendations for the Sedation-related Environment

- Units should comply with applicable federal and state laws regarding licensure and/or certification of all staff involved in the administration and monitoring of sedation and document training and competencies.
- Established discharge criteria should be attained before discharge from the endoscopy unit. Patients who received IV sedation during their endoscopic procedure should be discharged in the presence of a responsible individual. A written policy on discharge requirements should be documented.
- An agreement should exist between the unit and a hospital facility for the transfer of patients who require escalation of care. A written transfer agreement should be documented.
- A focused history and physical, including the patient's current medications and ASA classification, should be completed before the start of the procedure.[17]

Recommendations for Sedation-related Equipment

- All sedation-related equipment, before initial use and then then at intervals dictated by the manufacturer's guidelines, should be examined and verified to be in proper working order by a qualified biotechnician.[36]

- Oxygen, suction for the mouth, and electronic equipment that can monitor and display pulse, blood pressure, oxygen saturation and continuous electrocardiographic rhythm assessment should be available in the procedure room. A written policy for equipment checks and maintenance should be in place. A log to monitor compliance should be maintained.

Recommendations for Patient Monitoring

- All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (e.g., type of sedation, duration and complexity of procedure, patient condition). At a minimum, monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during procedure, during initial recovery, and just before discharge.[5]
- Units should have procedures in place to rescue patients who are sedated deeper than intended.[5, 17, 37, 38]
- When the target level is moderate sedation (also known as conscious sedation):
  - The individual assigned responsibility for patient monitoring may perform brief, interruptible tasks.[4, 5]
  - Minimal monitoring requirements include electronic assessment of blood pressure, respiratory rate, heart rate, and pulse oximetry combined with visual monitoring of the patient's level of consciousness and discomfort.
  - Currently, there are inadequate data to support the routine or required use of capnography during endoscopic procedures in adults where moderate sedation is the target.[5, 39, 40]
- When deep sedation is targeted:
  - The individual responsible for patient monitoring must be dedicated solely to that task and may not perform any other function during the procedure.[4, 5]
  - The use of capnography in EUS, ERCP, and colonoscopy to assess the adequacy of ventilation may reduce the incidence of hypoxemia and apnea,[41, 42] and its impact on the frequency of other sedation related adverse events such as bradycardia and hypotension is unknown. As such, capnography may be considered for the performance of endoscopy under deep sedation. However, there is no safety data to date to support the universal use of capnography in such cases.
  - Documentation of the clinical assessments and monitoring data during sedation and recovery is required.

Recommendations for Medications

- Written policies detailing the methods of drug storage, monitoring of drug inventory and expiration dates, and documentation of compliance with these policies are required.
- There should be an individual qualified by training and licensure (such as a physician or pharmacist) who is directly responsible for overseeing medication usage in the unit.

- Medications should be securely stored under environmental conditions consistent with the manufacturer's instructions on the label. The use of single-dose vials for all sedative and analgesic medications is strongly recommended.
- Controlled substances should be stored in a double-locked cabinet and a daily medication log compliant with state and federal regulations should be maintained. Disposal of unused narcotics and other controlled drugs should be witnessed by 2 individuals and documented.
- Medications should be given only under the order of the supervising physician or anesthesia professionals where applicable.
- Reversal agents for opioids and benzodiazepines should be readily available.
- A written policy should be in place for the identification, documentation and review of adverse drug reactions.

Recommendations for Emergency Management

- Appropriate pharmaceutical agents, oxygen, oral suction, laryngoscope, ambu bag, and defibrillator should be readily available in the unit.
- Units should train and periodically in-service staff in the use of equipment for emergency management.[4] Training and assessment of competency should be documented.

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Table 1

Summary of the key strategies to maintain safety in the gastrointestinal endoscopy unit

Each unit should have a designated flow for the safe physical movement of dirty endoscopes and other equipment.
Procedure rooms will vary in size with more complex procedures requiring greater space for more specialized equipment and in some cases, additional staff.
Before starting an endoscopic procedure, the patient, staff, and performing physician should verify the correct patient and procedure to be performed.
A specific infection prevention plan must be implemented and directed by a qualified person.
Gloves and an impervious gown should be worn by staff engaged in direct patient care during the procedure.
The unit should have a terminal cleansing plan that includes methods and chemical agents for cleansing and disinfecting the procedural space at the end of the day.
For patients undergoing routine endoscopy under moderate sedation a single nurse is required in the room in addition to the performing physician.
Complex procedures may require additional staff for efficiency, but not necessarily safety.
At a minimum, patient monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery and before discharge.
In cases where moderate sedation is the target, the individual responsible for patient monitoring may perform brief interruptible tasks.
In cases where moderate sedation is the target, there is currently inadequate data to support the routine use of capnography.